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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,054	08/30/2001	Seiichi Araki	109536-161	8743

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,054	ARAKI ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8* is/are allowed.

6)☒ Claim(s) *9-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Reissue Applications

Claims 1-54 are presented for examination.

The request for continued examination (RCE) filed December 28, 2005 has been received and entered.

The amendment filed December 28, 2005 proposes amendments to claims 9, 15, 18, 19, 25, 28, 29, 35, 38, 39, 44, 47, 48 and 52 that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Allowable Subject Matter

Claims 1-8 are allowable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating infections caused by *Escherichia coli* in a patient with a composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from amoxicillin, water-soluble polymers of claim 16, soy bean lecithin or yolk lecithin, proline, and glutamine administered in a form of intramuscular injection at proportions 10, 30 and 100 mg/kg , does not reasonably provide enablement for treating all types of infections caused by Gram-negative or Gram-positive bacteria, viruses, fungi, and

parasites; the composition formulation additives such as other antibiotics (broad), other water-soluble polymers (broad), and other lecithins (broad); administered intravenously, subcutaneously or orally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating infections by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, proline and glutamine.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, proline and glutamine are effective in treating all types of infections, and administered intravenously, subcutaneously and orally.

The breadth of the claims

The claims are very broad and inclusive to all types of infections caused by bacteria, viruses, fungi and parasites. Claims are very broad and inclusive to all types of antibiotics, water-soluble polymers and lecithins.

The amount of direction or guidance provided and the presence or absence of working examples

Example 1 shows riboflavin intramuscularly injected in a mouse infection with the *Escherichia coli* bacteria in proportions of 10, 30 and 100 mg/kg.

Example 2 shows a composition comprising riboflavin, glutamine and proline intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 3 shows sodium riboflavin phosphate (a derivative), intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 4 shows a composition comprising sodium riboflavin phosphate and amoxicillin (antibiotic) intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 5 shows a composition comprising riboflavin, polyvinyl pyrrolidone and sodium carboxymethyl cellulose (water-soluble polymers) and soy-bean lecithin and yolk lecithin (lecithin) intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

No examples showing the instant composition comprising riboflavin and/or riboflavin derivative one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, praline and glutamine are effective against infections caused by Gram-negative and Gram-positive bacteria, fungi, viruses, and parasites.

No examples showing the instant composition showing that all types of antibiotics can be used.

No examples showing the instant composition showing that all types of water-soluble polymers can be used.

No examples showing the instant composition showing all types of lecithin such as oatmeal, wheat germ or peanuts can be used.

No examples showing the instant composition can be administered intravenously, subcutaneously and orally.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the treating all types of infections caused by Gram-negative or Gram-positive bacteria; viruses, fungi, and parasites; the composition formulation additives such as other antibiotics (broad), other water-soluble polymers (broad), and other lecithins (broad); administered intravenously, subcutaneously or orally. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 9-54 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
February 13, 2006